1120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-6063-N6]

Medicare Program; National Expansion of the Prior Authorization Model for Repetitive,

Scheduled Non-Emergent Ambulance Transports

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the national expansion of the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports to all states, but we are delaying the implementation of the expansion to all additional states due to the COVID-19 Public Health Emergency. The model will continue to operate in the states currently participating in the model under section 1115A of the Social Security Act (the Act), which includes Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia. CMS will continue to monitor the Public Health Emergency and will provide public notice before implementing the model in additional states.

DATES: This national expansion begins on December 2, 2020 in Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia.

FOR FURTHER INFORMATION CONTACT:

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Questions regarding the national expansion of the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports should be sent to AmbulancePA@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. In the November 14, 2014 **Federal Register** (79 FR 68271), we published a notice entitled "Medicare Program; Prior Authorization of Repetitive, Scheduled Nonemergent Ambulance Transports," which announced the implementation of a 3-year Medicare prior authorization model under the authority of section 1115A of the Act that established a process for requesting prior authorization for repetitive, scheduled non-emergent ambulance transport rendered by ambulance suppliers garaged in three states (New Jersey, Pennsylvania, and South Carolina). These states were selected as the initial states for the model because of their high utilization and improper payment rates for these services. The model began on December 1, 2014, and was originally scheduled to end in all three states on December 1, 2017.

We chose to test this model on repetitive, scheduled non-emergent ambulance transports because these services have been historically vulnerable to improper payments. According to a study published by the Government Accountability Office in October 2012, entitled "Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased," the number of basic life support (BLS) non-emergent transports for Medicare Fee-For-Service beneficiaries increased by 59 percent from 2004 to 2010. A similar finding published by the Department of Health and Human Services' Office of Inspector General (OIG) in a 2006 study, entitled "Medicare Payments for Ambulance Transports," indicated a 20 percent nationwide improper payment rate for non-emergent ambulance transport. Likewise,

¹ Government Accountability Office "Ambulance Providers: Cost and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased" (GAO-13-6) (October 2012).

² Office of Inspector General "Medicare Payment for Ambulance Transport" (January 2006).

in June 2013, the Medicare Payment Advisory Commission published a report³ that included an analysis of non-emergent ambulance transports to dialysis facilities and found that, during the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined.

In the October 23, 2015 **Federal Register** (80 FR 64418), we published a notice titled "Medicare Program; Expansion of Prior Authorization for Repetitive, Scheduled Non-Emergent Ambulance Transports," which announced the inclusion of six additional states (Delaware, the District of Columbia, Maryland, North Carolina, West Virginia, and Virginia) in the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports in accordance with section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). These six states began participation on January 1, 2016, and the model was originally scheduled to end in all nine model states on December 1, 2017.

We extended the model for 3 additional years through December 1, 2020, as announced in the December 12, 2017 **Federal Register** (82 FR 58400), the December 4, 2018 **Federal Register** (83 FR 62577), and the September 16, 2019 **Federal Register** (84 FR 48620).

B. Expansion Criteria

Section 515(b) of MACRA (Pub. L. 114-10) added paragraph (16) to section 1834(l) of the Act, which requires that, beginning January 1, 2017, the Secretary expand the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports nationally to all states if an expansion to all states meets certain statutory requirements for expansion of models tested under section 1115A of the Act. These requirements are described in paragraphs (1) through (3) of section 1115A(c) of the Act, and include the following:

- The Secretary determines that such expansion is expected to—
- ++ Reduce spending under applicable title without reducing the quality of care; or
- ++ Improve the quality of patient care without increasing spending.

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³ Medicare Payment Advisory Commission, June 2013, pages 167-193.

- The Chief Actuary of CMS certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles.
- The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

To date, we have released two interim evaluation reports conducted by CMS contractor, Mathematica Policy Research. Most recently, the Second Interim Evaluation Report⁴ found that the model was successful in reducing repetitive, scheduled non-emergent ambulance transport spending and total Medicare spending while maintaining overall quality of and access to care. These findings were similar to the First Interim Evaluation Report.⁵ In comparison to groups of similar states, the model has reduced both repetitive, scheduled non-emergent ambulance transport use and expenditures, by 63 percent and 72 percent, respectively, in the model states, resulting in a reduction of approximately \$550 million in expenditures over 4 years for the population examined: beneficiaries with end-stage renal disease, severe pressure ulcers, or both. The evaluation reports found that the prior authorization model overall had no impact on quality measures or adverse events.

On March 28, 2018, the Chief Actuary of CMS certified that expansion of the model would reduce program spending under the Medicare program, thereby satisfying the requirements of section 1115A(c)(2) of the Act, stating that even under the most conservative assumptions, the projected savings from expansion would significantly outweigh the cost of administering the prior authorization policy.⁶

On May 29, 2019, the Secretary of the Department of Health and Human Services (the Secretary) determined that the model met the statutory criteria for expansion under sections

⁴ https://innovation.cms.gov/data-and-reports/2020/rsnat-secondintevalrpt

⁵ https://innovation.cms.gov/files/reports/rsnat-firstintevalrpt.pdf

 $^{^6\} https://www.cms.gov/files/document/certification-medicare-prior-authorization-model-repetitive-scheduled-non-emergent-ambulance.pdf$

1115A(c)(1) and (c)(3) of the Act. CMS is therefore required under section 1834(l)(16) of the Act, as added by section 515(b) of MACRA (Pub. L. 114-10), to expand the model nationwide.

C. Medicare Ambulance Benefit

Medicare may cover ambulance services, including ground (land and water) and air ambulance (fixed-wing and rotary-wing) transport services, only if the ambulance transport service is furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated, to the nearest appropriate facility. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Non-emergent transportation by ambulance is appropriate if either the-- (1) beneficiary is bed-confined and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) beneficiary's medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of non-emergent ambulance transportation; rather, it is one factor that is considered in medical necessity determinations.⁷

A repetitive ambulance service is defined as medically necessary ambulance transportation that is furnished in 3 or more round trips during a 10-day period, or at least 1 round trip per week for at least 3 weeks.⁸ Repetitive ambulance services are often needed by beneficiaries receiving dialysis or cancer treatment.

Medicare may cover repetitive, scheduled non-emergent transportation by ambulance if the-- (1) medical necessity requirements described previously are met; and (2) ambulance provider/supplier, before furnishing the service to the beneficiary, obtains a written order from

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⁷ 42 CFR 410.40(d)(1).

⁸ Program Memorandum Intermediaries/Carriers, Transmittal AB-03-106.

the beneficiary's attending physician certifying that the medical necessity requirements are met (see 42 CFR 410.40(e)(1) and (2)).9

In addition to the medical necessity requirements, the service must meet all other Medicare coverage and payment requirements, including requirements relating to the origin and destination of the transportation, vehicle and staff, and billing and reporting. Additional information about Medicare coverage of ambulance services can be found in 42 CFR 410.40, 410.41, and in the Medicare Benefit Policy Manual (Pub. 100-02), Chapter 10, at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf.

II. Provisions of the Notice

This notice announces the national expansion of the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports to all states under section 1834(I)(16) of the Act, as added by section 515(b) of MACRA (Pub. L. 114-10). Due to the COVID-19 Public Health Emergency, we are delaying the implementation of the expansion to all additional states. The Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports currently operating under section 1115A of the Act will transition to the national model on December 2, 2020. This transition will include independent ambulance suppliers garaged in Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia. CMS will continue to monitor the Public Health Emergency and will provide public notice before implementing the model in additional states.

We will continue to test whether prior authorization helps reduce expenditures, while maintaining or improving quality of care, using the prior authorization process described in this notice to reduce utilization of services that do not comply with Medicare policy. Prior authorization helps ensure that all relevant clinical or medical documentation requirements are

⁹ Per 42 CFR 410.40(e)(2), the physician's order must be dated no earlier than 60 days before the date the service is furnished.

met before services are furnished to beneficiaries and before claims are submitted for payment. It further helps to ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The national expansion of the model will follow a similar design as the Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transports that operated under section 1115A of the Act. The use of prior authorization does not create new clinical documentation requirements. Instead, it requires the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization also allows ambulance suppliers to address coverage issues prior to furnishing services. Hospital-based ambulance providers that are owned or operated by a hospital or both, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program have not been included in the current model, and are not included in the national model and should not request prior authorization.

For the national expansion of the model, the prior authorization process will apply in all states and the District of Columbia to the following Healthcare Common Procedure Coding System (HCPCS) codes for Medicare payment:

- A0426 Ambulance service, advanced life support, non-emergency transport, Level 1
 (ALS1).
 - A0428 Ambulance service, BLS, non-emergency transport.

While prior authorization is not needed for the mileage code, A0425, a prior authorization decision for an A0426 or A0428 code will automatically include the associated mileage code.

Submitting a prior authorization request is voluntary. However, an ambulance supplier or beneficiary is encouraged to submit to the Medicare Administrative Contractor (MAC) a request for prior authorization along with all relevant documentation to support Medicare coverage of a repetitive, scheduled non-emergent ambulance transport. If prior authorization has not been requested by the fourth round trip in a 30-day period, the subsequent claims will be stopped for

prepayment review.

In order for a prior authorization request to be provisionally affirmed, the request for prior authorization must meet all applicable rules and policies, including any local coverage determination (LCD) requirements for ambulance transport claims. A provisional affirmation is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements. After receipt of all relevant documentation, the MAC will make every effort to conduct a review and postmark the notification of their decision on the prior authorization request within 10 business days. Notification will be provided to the ambulance supplier and to the beneficiary. If a prior authorization request is non-affirmed, the request can be resubmitted with additional documentation. Unlimited resubmissions are allowed.

An ambulance supplier or beneficiary may request an expedited review when the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. If the MAC agrees that the standard review timeframe would put the beneficiary at risk, the MAC will make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable Medicare-required documentation. As this model is for non-emergent services only, we expect requests for expedited reviews to be extremely rare.

A provisional affirmative prior authorization decision may affirm a specified number of trips within a specific amount of time. The prior authorization decision, justified by the beneficiary's condition, may affirm up to 40 round trips (which equates to 80 one-way trips) per prior authorization request in a 60-day period. Alternatively, a provisional affirmative decision may affirm less than 40 round trips in a 60-day period, or may affirm a request that seeks to provide a specified number of transports (40 round trips or less) in less than a 60-day period. A provisional affirmative decision can be for all or part of the requested number of trips.

Transports exceeding 40 round trips (or 80 one-way trips) in a 60-day period require an additional prior authorization request.

The MAC may consider an extended affirmation period for beneficiaries with a chronic condition that is deemed not likely to improve over time. The prior authorization decision, justified by the beneficiary's chronic condition, may affirm up to 120 round trips (which equates to 240 one-way trips) per prior authorization request in a 180-day period. The medical records must clearly indicate that the condition is chronic, and the MAC must have established through two previous prior authorization requests that the beneficiary's medical condition has not changed or has deteriorated from previous requests before allowing an extended affirmation period.

The following describes examples of various prior authorization scenarios:

- Scenario 1: When an ambulance supplier or beneficiary submits a prior authorization request to the MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the ambulance transport, the MAC will send a provisional affirmative prior authorization decision to the ambulance supplier and the beneficiary. When the subsequent claim is submitted to the MAC by the ambulance supplier, it is linked to the prior authorization decision via the claims processing system, and the claim will be paid so long as all Medicare coding, billing, and coverage requirements are met. A claim could be denied for technical reasons, however, such as a duplicate claim or a date of service after a deceased beneficiary's date of death. CMS contractors may conduct targeted prepayment and post payment reviews to ensure that claims are accompanied by documentation not required or available during the prior authorization process. In addition, it is possible that the Comprehensive Error Rate Testing (CERT) contractor may select a claim linked to an affirmed prior authorization decision for review as the CERT contractor must review a random sample of claims for purposes of estimating the Medicare improper payment rate.
- <u>Scenario 2</u>: When an ambulance supplier or beneficiary submits a prior authorization request, but all relevant Medicare coverage requirements are not met, the MAC will send a non-affirmative prior authorization decision to the ambulance supplier and to the beneficiary

advising them that Medicare will not pay for the service. The supplier or beneficiary may then resubmit the request with additional documentation showing that Medicare requirements have been met. Alternatively, an ambulance supplier could furnish the service and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The ambulance supplier and the beneficiary would then have the Medicare denial for secondary insurance purposes, and would have the opportunity to submit an appeal of the claim denial if they believe Medicare coverage was denied inappropriately.

- <u>Scenario 3</u>: When an ambulance supplier or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the ambulance supplier and to the beneficiary, with an explanation of what information is missing. The ambulance supplier or beneficiary can rectify the error(s) and resubmit the prior authorization request with appropriate documentation.
- Scenario 4: If an ambulance supplier renders a service to a beneficiary and does not request prior authorization by the fourth round trip in a 30-day period, and the claim is submitted to the MAC for payment, then the claim will be stopped for prepayment review and documentation will be requested.
- ++ If the claim is determined to be for services that were not medically necessary or for which there was insufficient documentation, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The ambulance supplier or the beneficiary, or both, can appeal the claim denial if they believe the denial was inappropriate.
 - ++ If the claim is determined to be payable, it will be paid.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial ambulance supplier cannot complete the total number of prior authorized transports (for example, the initial ambulance company closes or no longer services that area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required

documentation in the submission. If multiple ambulance suppliers are providing transports to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the ambulance supplier indicated in the provisionally affirmed prior authorization request. Any ambulance supplier submitting claims for repetitive, scheduled non-emergent ambulance transports for which no prior authorization request is submitted by the fourth round trip in a 30-day period will be subject to 100 percent prepayment medical review of those claims.

We will expand outreach and education efforts to all states and the District of Columbia on this prior authorization model to ambulance suppliers, as well as beneficiaries, through such methods as an operational guide, frequently asked questions (FAQs) on our website, a physician letter explaining the ambulance suppliers' need for the proper documentation, and educational events and materials issued by the MACs.

We will work to limit any adverse impact on beneficiaries and to educate beneficiaries about the model process. If an ambulance supplier submits a claim associated with a non-affirmed prior authorization decision, it will be denied and beneficiaries will continue to have all applicable administrative appeal rights.

Additional information is available on the CMS website athttp://go.cms.gov/PAAmbulance.

III. Collection of Information Requirements

As required by chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), the information collection burden associated with this national model is currently approved under OMB control number 0938-1380 which expires on August 31, 2023.

IV. Regulatory Impact Statement

This document announces an expansion of the 3-year Medicare Prior Authorization

Model for Repetitive Scheduled Non-emergent Ambulance Transport. Therefore, there are no

regulatory impact implications associated with this notice.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema

Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the

Federal Register Liaison, to electronically sign this document for purposes of publication in the

Federal Register.

Authority: Section 1834(1)(16) of the Social Security Act (the Act), as added by section 515(b)

of MACRA (Pub. L. 114-10)

Dated: November 17, 2020.

Lynette Wilson,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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